

ATTORNEY'S DOCKET NUMBER: 0492611-0580 (MIT 7442)
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Langer, <i>et al.</i>	Examiner:	Azpuru
Serial No.:	09/724,382	Art Unit:	1615
Filing Date:	November 28, 2000	Confirmation No.:	9451
Title:	SEMI-INTERPENETRATING OR INTERPENETRATING POLYMER NETWORKS FOR DRUG DELIVERY AND TISSUE ENGINEERING		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

We, Kristi S. Anseth, Jennifer H. Elisseeff, Robert S. Langer, and Derek Sims, declare as follows:

1. We are joint inventors on the present application, U.S.S.N. 09/724,382, which was filed on November 28, 2000, and claims priority to U.S.S.N. 08/862,740, filed on May 23, 1997, and U.S.S.N. 60/041,881, filed on April 11, 1997. The currently pending claims in the present application relate to methods of making semi-interpenetrating or interpenetrating polymer networks or methods of forming a tissue equivalent in a subject or a mold.

2. U.S. Patent No. 5,902,599 was filed on February 20, 1996 ("the Anseth patent"). The Anseth patent names Kristi S. Anseth, Robert S. Langer, and Venkatram R. Shastri as inventors.

3. The Anseth patent discloses, at column 8, lines 7-11: "In orthopedic applications, bone regenerating molecules, seeding cells, and/or tissue can be incorporated into the prepolymer prior to or after polymerization, or may be applied prior to or after formation of the implant at the site of implantation."

4. The subject matter of currently pending claims 12-23 (attached) in the present application, U.S.S.N. 09/724,382, was invented solely by us. To the extent that the Anseth

patent discloses but does not claim the subject matter of any of these claims, as indicated by paragraph 3 above, we declare that such subject matter originated with us.

5. We declare that all statements made herein of our own knowledge are true and that these statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are made punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patents that may issue thereon.

Date: Nov. 14, 2008

Signature: Kristi S. Anseth
Kristi S. Anseth

Date: _____

Signature: _____
Jennifer H. Elisseeff

Date: _____

Signature: _____
Robert S. Langer

Date: _____

Signature: _____
Derek Sims

Pending Claims in U.S.S.N. 09/724,382

12. A method for making semi-interpenetrating or interpenetrating polymer networks, comprising: exposing a suspension of dissociated cells in a solution of two or more biocompatible polymers to free radicals generated during photopolymerization using a light source external to the suspension so that the light generates free radicals thereby forming the semi-interpenetrating or interpenetrating polymer networks.

13. The method of Claim 12, wherein the semi-interpenetrating or interpenetrating polymer networks are cartilage tissue equivalents.

14. The method of Claim 13 wherein the light is selected from the group consisting of, ultraviolet radiation, long-wavelength ultraviolet radiation, and visible light.

15. The method of Claim 13 wherein the suspension further comprises a photoinitiator.

16. The method of Claim 15 wherein the photoinitiator is selected from the group consisting of erythrosin, phloxime, rose bengal, thionine, camphorquinone, ethyl eosin, eosin, methylene blue, riboflavin, 2,2-dimethyl-2-phenylacetophenone, 2-methoxy-2-phenylacetophenone, 2,2-dimethoxy-2-phenylacetophenone, and other acetophenone derivatives.

17. The method of Claim 16 wherein the suspension further comprises a cocatalyst.

18. The method of Claim 17 wherein the cocatalyst is selected from the group consisting of N-methyl diethanolamine, N,N-dimethyl benzylamine, triethanolamine, triethylamine, dibenzylamine, N-benzylethanolamine, and N-isopropyl benzylamine.

19. The method of Claim 18 wherein the cocatalyst is triethanolamine.

20. A method of forming a tissue equivalent in a subject, the tissue equivalent comprising semi-interpenetrating or interpenetrating networks, comprising:

injecting a suspension of dissociated cells in a solution of two or more biocompatible polymers into a subject, and

exposing the suspension to free radicals generated during photopolymerization using a light source external to the injected suspension so that the light penetrates through tissue to generate free radicals thereby forming the tissue equivalent.

21. The method of Claim 20 wherein the x-rays, ultrasound, infrared radiation, far infrared radiation, ultra-violet radiation, long-wavelength ultraviolet radiation, or visible light is applied externally to the skin.

22. The method of Claim 20 wherein the light is selected from the group consisting of ultra-violet radiation, long-wavelength ultraviolet radiation, or visible light and is applied within a synovial space to a polymer-cell suspension injected into an adjacent joint.

23. A method of forming a tissue equivalent in a mold, the tissue equivalent comprising semi-interpenetrating or interpenetrating polymer networks, comprising:

injecting a suspension of dissociated cells in a solution of two or more biocompatible polymers into a mold, and

exposing the suspension to free radicals generated during photopolymerization using a light source external to the suspension so that the electromagnetic radiation generates free radicals thereby forming the tissue equivalent.

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DECLARATION UNDER 37 C.F.R. § 1.132

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1. We are joint inventors on the present application, U.S.S.N. 09/724,382, which was filed on November 28, 2000, and claims priority to U.S.S.N. 08/862,740, filed on May 23, 1997, and U.S.S.N. 60/041,881, filed on April 11, 1997. The currently pending claims in the present application relate to methods of making semi-interpenetrating or interpenetrating polymer networks or methods of forming a tissue equivalent in a subject or a mold.
2. U.S. Patent No. 5,902,599 was filed on February 20, 1996 ("the Anseth patent"). The Anseth patent names Kristi S. Anseth, Robert S. Langer, and Venkatram R. Shastri as inventors.
3. The Anseth patent discloses, at column 8, lines 7-11: "In orthopedic applications, bone regenerating molecules, seeding cells, and/or tissue can be incorporated into the prepolymer prior to or after polymerization, or may be applied prior to or after formation of the implant at the site of implantation."
4. The subject matter of currently pending claims 12-23 (attached) in the present application, U.S.S.N. 09/724,382, was invented solely by us. To the extent that the Anseth


patent discloses but does not claim the subject matter of any of these claims, as indicated by paragraph 3 above, we declare that such subject matter originated with us.

5. We declare that all statements made herein of our own knowledge are true and that these statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are made punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patents that may issue thereon.

Date: _____

Signature: _____
Kristi S. Anseth

Date: 12/11/08

Signature: 
Jennifer H. Elisseeff

Date: _____

Signature: _____
Robert S. Langer

Date: _____

Signature: _____
Derek Sims

Pending Claims in U.S.S.N. 09/724,382

12. A method for making semi-interpenetrating or interpenetrating polymer networks, comprising: exposing a suspension of dissociated cells in a solution of two or more biocompatible polymers to free radicals generated during photopolymerization using a light source external to the suspension so that the light generates free radicals thereby forming the semi-interpenetrating or interpenetrating polymer networks.

13. The method of Claim 12, wherein the semi-interpenetrating or interpenetrating polymer networks are cartilage tissue equivalents.

14. The method of Claim 13 wherein the light is selected from the group consisting of, ultraviolet radiation, long-wavelength ultraviolet radiation, and visible light.

15. The method of Claim 13 wherein the suspension further comprises a photoinitiator.

16. The method of Claim 15 wherein the photoinitiator is selected from the group consisting of erythrosin, phloxime, rose bengal, thionine, camphorquinone, ethyl eosin, eosin, methylene blue, riboflavin, 2,2-dimethyl-2-phenylacetophenone, 2-methoxy-2-phenylacetophenone, 2,2-dimethoxy-2-phenylacetophenone, and other acetophenone derivatives.

17. The method of Claim 16 wherein the suspension further comprises a cocatalyst.

18. The method of Claim 17 wherein the cocatalyst is selected from the group consisting of N-methyl diethanolamine, N,N-dimethyl benzylamine, triethanolamine, triethylamine, dibenzylamine, N-benzylethanolamine, and N-isopropyl benzylamine.

19. The method of Claim 18 wherein the cocatalyst is triethanolamine.

20. A method of forming a tissue equivalent in a subject, the tissue equivalent comprising semi-interpenetrating or interpenetrating networks, comprising:

injecting a suspension of dissociated cells in a solution of two or more biocompatible polymers into a subject, and

exposing the suspension to free radicals generated during photopolymerization using a light source external to the injected suspension so that the light penetrates through tissue to generate free radicals thereby forming the tissue equivalent.

21. The method of Claim 20 wherein the x-rays, ultrasound, infrared radiation, far infrared radiation, ultra-violet radiation, long-wavelength ultraviolet radiation, or visible light is applied externally to the skin.

22. The method of Claim 20 wherein the light is selected from the group consisting of ultra-violet radiation, long-wavelength ultraviolet radiation, or visible light and is applied within a synovial space to a polymer-cell suspension injected into an adjacent joint.

23. A method of forming a tissue equivalent in a mold, the tissue equivalent comprising semi-interpenetrating or interpenetrating polymer networks, comprising:

injecting a suspension of dissociated cells in a solution of two or more biocompatible polymers into a mold, and

exposing the suspension to free radicals generated during photopolymerization using a light source external to the suspension so that the electromagnetic radiation generates free radicals thereby forming the tissue equivalent.

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Date: _____

Signature: _____
Kristi S. Anseth

Date: _____

Signature: _____
Jennifer H. Elisseeff

Date: 11/14/08

Signature:  _____
Robert S. Langer

Date: _____

Signature: _____
Derek Sims

Pending Claims in U.S.S.N. 09/724,382

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13. The method of Claim 12, wherein the semi-interpenetrating or interpenetrating polymer networks are cartilage tissue equivalents.

14. The method of Claim 13 wherein the light is selected from the group consisting of; ultraviolet radiation, long-wavelength ultraviolet radiation, and visible light.

15. The method of Claim 13 wherein the suspension further comprises a photoinitiator.

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Date: _____

Signature: _____
Kristi S. Anseth

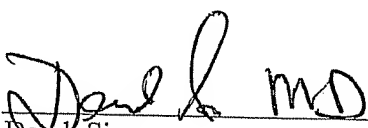
Date: _____

Signature: _____
Jennifer H. Elisseeff

Date: _____

Signature: _____
Robert S. Langer

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Signature:  _____
Derek Sims

Pending Claims in U.S.S.N. 09/724,382

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13. The method of Claim 12, wherein the semi-interpenetrating or interpenetrating polymer networks are cartilage tissue equivalents.

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